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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,285	07/22/2004	Ian Richard Catchpole	PG4745	9183
20462 7590 11/19/2008 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
			EXAMINER ELLIS, SUEZZU Y	
			ART UNIT 2876	PAPER NUMBER
			NOTIFICATION DATE 11/19/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/502,285

**Applicant(s)**

CATCHPOLE, IAN RICHARD

**Examiner**

Suezu Ellis

**Art Unit**

2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **FINAL REJECTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities:  
  
Claim language recites the term "gultathione". Correct spelling should be "glutathione". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dalton et al. (US 2004/0049150) in view of Johnson et al. (US 2002/0032165) and Herbert (US 2002/0002136)

With respect to claim 1, Dalton et al. discloses a DNA pharmaceutical agent delivery device having at least one skin-piercing microneedle which comprises a

support coated with a solid reservoir medium containing a DNA pharmaceutical agent (DNA vaccine) [0025], [0061]-[0065].

Dalton et al. fails to expressly disclose the inclusion of glutathione in the solid reservoir medium.

Johnson et al. teaches a composition for a DNA delivery system where the composition can comprise glutathione [0031], [0059].

It would have been obvious to one of ordinary skill in the art to include glutathione in the solid reservoir medium of Cormier et al. in order to function as a free radical scavenger (quench free radicals) thereby stabilizing the DNA, as taught by Herbert [0006], [0009].

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cormier et al. (US 2002/0177839) in view of Johnson et al. and Herbert.

With respect to claim 1, Cormier et al. discloses a DNA pharmaceutical agent delivery device having at least one skin-piercing microneedle (microprojection) which comprises a support (microprojection itself) coated with a solid reservoir medium (solid coating) containing a DNA pharmaceutical agent [0049]; claims 8, 35 and 62; Fig. 2.

Cormier et al. fails to expressly disclose the inclusion of glutathione in the solid reservoir medium.

Johnson et al. teaches a composition for a DNA delivery system where the composition can comprise glutathione [0031], [0059].

It would have been obvious to one of ordinary skill in the art to include glutathione in the solid reservoir medium of Cormier et al. in order to function as a free radical scavenger (quench free radicals) thereby stabilizing the DNA, as taught by Herbert [0006], [0009].

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Prausnitz et al. (US 6,743,211) discloses a DNA pharmaceutical agent delivery device having at least one skin-piercing microneedle which comprises a support coated with a solid reservoir medium containing a DNA pharmaceutical agent.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone/Fax Information***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615  
16 November 2008